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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/460,107 12/13/99 ASTLE

T 130-129

021091  
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HM22/0426

EXAMINER

LU, F

ART UNIT

PAPER NUMBER

1655

3

DATE MAILED:

04/26/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/460,107

Applicant(s)

Astle

Examiner

Frank Lu

Group Art Unit

1655



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 1-11 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 12-28 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-28 are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Location of Application***

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1655.

### ***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a method of performing a reagent protocol using polymerase chain reaction in class 435, subclass 91.2.
  - II. Claims 12-28, drawn to an apparatus for performing a reagent protocol using polymerase chain reaction, classified in class 435, subclass 287.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus such as any regular PCR instrument.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. John Crozier (registration No.30, 371) on April 14, 2000 a provisional election was made with traverse to prosecute the invention of Group II, claims 12-28. Affirmation of this election must be made by applicant in responding to this office action. Claims 1-7, 13-18, 23-25, and 30-33 are withdrawn from further consideration by the examiner, 37 CAR 1.142 (b), as being drawn to a non-elected invention.

### ***Drawings***

3. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

### ***Specification***

4. The disclosure is objected to because of the following informalities: US Patent No. and issued date on line 4, 5, and 8 of page 2 are missing. Please check the specification for mistakes.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands* 858 F. 2d 731, 8 USPQ2nd 1400 (CAFC 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'". Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. " Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations". Enablement is considered in view of the *wands* factors (MPEP 2164.01(a)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the

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nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*The Quantity of Experimentation Necessary & The Amount of Direction or Guidance Provided*

Claims 12-28 in this instant application are directed to an apparatus for performing a reagent protocol using polymerase chain reaction.

The claims have sufficient breadth of scope so to encompass an automated apparatus for performing a reagent protocol using polymerase chain reaction with any size of reagent wells. The specification does not provide adequate guidance for use of size of reagent wells in an apparatus for performing a reagent protocol using polymerase chain reaction. The specification does not enable the making of the apparatus for performing a reagent protocol using polymerase chain reaction with undefined size of reagent wells.

The claims have sufficient breadth of scope so to encompass automated control means. The specification does not set forth any software by which such an apparatus is to be operational, nor set forth a flow diagram as to the manner the device is to operate nor set forth guidance as to how prior art software should be/could be modified in order to enable the operation of the apparatus.

Note that the specification does not provide adequate guidance to teach how to perform the polymerase chain reaction such as how to loading and unloading of the machine and how to set up a program of a polymerase chain reaction. It is impossible how the skilled artisans at the

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time of invention was made perform a polymerase chain reaction without these guidances.

Clearly, the skilled artisan would have to resort to various methods to use this apparatus with little success. Such efforts constitute undue experimentation. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ ‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’). ”

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

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Note that these undue experimentations will include but not limit to: (1) redesign a reagent well with a size which fit the protocol of polymerase chain reaction; (2) set forth a software by which such an apparatus is to be operational; (3) how to loading and unloading of the machine and how to set up a program of a polymerase chain reaction. These undue experimentations would required several years to complete.

*The Presence or Absence of Working Examples*

The specification does not provide any working example.

*The Nature of the Invention*

The invention relates to an automated apparatus for performing a reagent protocol using polymerase chain reaction.

*The State of the Prior Art*

At the time of filing, an apparatus with water controlled high-speed thermal cycling system for polymerase chain reaction had been built (US Patent 5,508,197, filled on July 25, 1994). However, an apparatus for performing a reagent protocol using polymerase chain reaction with any size of reagent wells and without computer controlled thermal cycling system is a novel and an undeveloped are of the art.

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*The Relative Skill of Those in the Art*

The relative skill of those in the art to which the invention most closely pertains is high, on par with those which hold a Ph.D. in biochemistry and computer biology.

*The Predictability or Unpredictability of the Art*

The predictability of the art is low. Further, the claimed invention relates directly to matters of physiology and chemistry which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

*The Breadth of the Claims*

The claims are broad. The claims encompass an automated apparatus for performing a reagent protocol using polymerase chain reaction with any size of reagent wells and without computer controlled thermal cycling system. In view of the limited guidance and the acknowledged areas of difficulty, applicant is urged to consider narrowing the scope of the claims to that which attention has been directed.

7. Claims 12-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is note that the specification does not provide an adequate written description of automated control (computer) means as a part of the apparatus for polymerase chain reaction since the specification does not have any description about how to use computer to control thermal cycling system and other element of the apparatus, and how to set up a program for polymerase chain reaction (see specification, pages 11 and 13).

In order for the skilled artisan to practice the full scope of the invention, sd. skilled artisan would have to resort to undue experimentation, these experiments can not be performed with the guidance provided by the application.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 12-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 12-28 are rejected as vague and indefinite over the phrase “ means to index patterns of reagent wells or means to index said patterns of reagent wells ” in steps (a) and (b) of claim 12 because it is unclear how an apparatus can mean to (a) and (b) in the same time. The

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rejection can be overcome by clarifying the meaning of means to index patterns of reagent wells or means to index said patterns of reagent wells ”.

11. The term "thermoplastic web" in claims 14-17, 19 and 28 is a relative term which renders the claim indefinite. The term "thermoplastic web" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

12. The term "single or multiple well pipettor" in claims 21, 22, and 27 is a relative term which renders the claim indefinite. The term "single or multiple well pipettor" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. The term "specific time controlled period" in claim 26 is a relative term which renders the claim indefinite. The term "specific time controlled period" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

14. Claims 12-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a computer temperature controlled system in the apparatus for polymerase chain reaction.

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***Conclusion***

15. No Claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

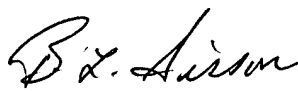
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu

April 20, 2000

  
BRADLEY L. SISSON  
PRIMARY EXAMINER  
GROUP 1800/1650  
4/22/2000